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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,568	11/13/2003	Norbert Hofgen	HUBR-1253-US	1757
24972	7590	05/22/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			SHAMEEM, GOLAM M	
			ART UNIT	PAPER NUMBER

1626

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/714,568

Applicant(s)

HOFGEN ET AL.

Examiner

Golam M. M. Shameem, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 42-63 is/are pending in the application.  
4a) Of the above claim(s) 58-63 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 42-49 is/are rejected.  
7) ☒ Claim(s) 50-57 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/16/2004.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

This application claims the benefit for foreign priority under 35 U.S.C. § 119(a)-(d) to Germany 102 53 426.8 11/15/2002 is acknowledged.

### ***Status of Claims***

Claims 42-63 are currently pending in the application. Claims 1-41 were canceled.

Receipt is acknowledged of Applicant's response filed on April 05, 2006 and that has been entered.

Claims 58-63 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

### ***Information Disclosure Statement***

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 04/16/2004, which has been entered in the file.

### ***Response to Election/Restriction***

In response to the restriction requirement, Applicants have elected Group I, which includes claims 42-49 drawn to a compound of formula 1 and the elected species as set forth found in claim 49 with traverse is acknowledged. The traversal is on the ground(s) that all the pending claims should be rejoined and examined with the elected Group I because "it would not be undue burden on the Examiner to search" (Remarks, page 9) and therefore, a search and examination of the entire Markush group should be made without a serious burden.

Applicant's arguments are fully considered and found partially persuasive and therefore, Examiner has agreed to modify the restriction requirements to include and examine Group II and

III (claims 50-57) together to the elected invention of Group I. However, the Examiner respectfully disagrees with the Applicant's other arguments because the products of Invention groups I-VI differ materially in structure and in element from each other and therefore, are capable of supporting their own patents. The invention groups I-VI are related to a set of structurally diverse and dissimilar compounds, compositions, process of preparation and their methods of uses (chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly), which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Because of many classes and subclasses in each of the Group, a separate search considerations are involved, which would impose a serious burden on the Examiner to perform a complete search of the defined areas if unrestricted. Also the fields of search are not coextensive. The wide disparity among the groups requires that many divergent fields must be searched, including all classes and subclasses of U.S. and foreign patents as well as journals and publications. Moreover, the Examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the Examiner. Nevertheless, Examiner may reconsider to rejoin method of use claims commensurate in scope with the product claims when the case would be found in condition for allowance [provided those method claims are free from 35 U.S.C. §112 first (including written description, reach-through claim language and/or scope-enablement issues) and second paragraphs]. For these reasons, Applicant's arguments are found unpersuasive and, therefore, the requirement for restriction and election of species is still deemed proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42-49 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-4 of US 6,251,923, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are drawn to the same art recognized subject matter. A reference anticipating one set of claims will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since Hofgen *et al* teach the generic compounds and compositions which are similar to the instantly claimed compounds and compositions.

The subject matter claimed in the instant application is fully disclosed and covered in US 6,251,923. Therefore, the disclosure of Hofgen *et al* that teach many permutation and combinations [including various Markush variable substitutions, such as R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>5</sup> (which is pyridyl)] etc, which would easily place Applicant's invention in possession of the public at the time of Applicant's invention was filed. The indiscriminate selection of "some"

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among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). Therefore, in the instant case, one skilled in the chemical art would be motivated to choose to replace variable substitutions (such as R<sup>2</sup> and R<sup>3</sup> are pyridyl) in permutation and combinations in core structure to obtain the desired products in view of the known teaching of the art. The claimed compounds are so closely related structurally to the homologous and /or analogous compounds of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Moreover, any other differences are but obvious structural modifications, which would be apparent to one skilled in the chemical art that can use similar substitutions, would expect to have the same or essentially the same results. Therefore, in looking at the instant claimed compounds as a whole, the claimed compounds would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker *et al* (1990) and further in view of Dillard *et al* (1996).

Applicant claims hydroxyindole derivatives, their uses and process for preparing them.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

Baker *et al* and Dillard *et al* both teach the analogous compounds to those instantly claimed invention having similar therapeutic utility.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the claimed compounds and that of the reference herein lies in the selection of different substitutions in core indole ring, such as having -H or -OH in R<sup>4</sup> and R<sup>5</sup> position of the instantly claimed compound instead of Me (methyl) or OH for the same position in the prior art (RN 125818-12-4 and RN 185501-87-5, HCAPLUS database, a copy is provided herewith) assuming R<sup>1</sup> is alkyl or substituted alkyl, R<sup>2</sup> and R<sup>3</sup> are both hydrogen for instantly claimed compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

It is well established that the substitution of hydrogen for alkyl on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and *In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The disclosure of Baker *et al* and Dillard *et al* that teach several combinations, which would easily place Applicants invention in possession of the public at the time of Applicant's invention was filed. Therefore, in the instant case, one skilled in the art would be motivated to choose to replace a methyl group with a hydrogen atom or vice versa in view of the known teaching of the art. The claimed compounds are so closely related structurally to the homologous compounds of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Since the core indole ring of compound is not novel and the novelty (if there is any) belongs to the selection of different variable substitutions, a great caution should be exercised to determine the patentability of the claimed invention. Therefore, in looking at the

instant claimed compounds as a whole, the claimed compounds would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

### ***Objections***

Claims 50-57 are objected to as being dependent upon a rejected base claim 42, but would be allowable (after filing Terminal Disclaimer) if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golem Shamed, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKean, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is 571-273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet



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e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golem M. M. Shameem, Ph.D.  
Primary Examiner  
Art Unit 1626,  
Technology Center 1600

A handwritten signature in black ink, appearing to read "G. M. Shameem", with a stylized flourish at the end.

**GOLAM M. M. SHAMEEM, PH.D**  
**PRIMARY EXAMINER**

April 14, 2006